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### Responding to Biological Attacks

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## RESPONDING TO BIOLOGICAL ATTACKS

BY BARRY KELLMAN\*

In 2001, powdered anthrax in envelopes disrupted the government, cost billions to clean up, and killed five people.<sup>1</sup> Terrorist groups such as Aum Shunriky, which released sarin gas in the Tokyo subway experimented with biological weapons.<sup>2</sup> Al Qaida built an anthrax lab in Afghanistan in the 1990s.<sup>3</sup> Experts are concerned that future bio-attacks could lead to dire consequences substantially exceeding anything other than nuclear weapons – hundreds of thousands of casualties, trillions of dollars in losses, and exceptional levels of panic.<sup>4</sup> In 2008, the Commission on Prevention of Weapons of Mass Destruction Proliferation and Terrorism asserted that bio-attacks are the most likely catastrophic threat to humanity.<sup>5</sup>

How should the government be ready to respond to a catastrophic bio-attack that no one knows when, where, or even whether it will occur? It is useful to break down this question into three principle components. First, how can responders quickly and accurately know what agent has been used so that they can respond? Second, how can responders obtain sufficient medication to treat affected populations against whichever agent that has been used? Third, how can responders effectively limit the damage and restore order? Dozens of U.S. government agencies and programs have relevant and often overlapping responsibilities without centralized oversight – a bureaucratic condition that makes it difficult for people inside and outside government to understand what is exactly going on.<sup>6</sup>

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<sup>1</sup> Kimberly M. Thompson et al., *Bayes, Bugs, and Bioterrorists: Lessons Learned from the Anthrax Attacks*, CTR. TECH. & NAT'L SEC. POL'Y NAT'L DEF. U. (Apr. 2005), <http://www.dtic.mil/dtic/tr/fulltext/u2/a435051.pdf>.

<sup>2</sup> Holly Fletcher, *Aum Shinrikyo*, COUNCIL ON FOREIGN REL. (June 2012), <https://www.cfr.org/backgrounder/aum-shinrikyo>.

<sup>3</sup> Michael R. Gordon, *A Nation Challenged: Weapons; US Says it Found Qaeda Lab Being Built to Produce Anthrax*, N.Y. TIMES (Mar. 2002), <https://www.nytimes.com/2002/03/23/world/nation-challenged-weapons-us-says-it-found-qaeda-lab-being-built-produce-anthrax.html>.

<sup>4</sup> Ben Farmer, *Bioterrorism Could Kill More People than Nuclear War, Bill Gates to Warn World Leaders*, THE TELEGRAPH (Feb. 18, 2017), <https://www.telegraph.co.uk/news/2017/02/17/biological-terrorism-could-kill-people-nuclear-attacks-bill/>.

<sup>5</sup> Graham Allison et al., *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism*, COMM'N ON PREVENTION OF WEAPONS OF MASS DESTRUCTION, PROLIFERATION & TERRORISM (Dec. 2008), <https://apps.dtic.mil/dtic/tr/fulltext/u2/a510559.pdf>.

<sup>6</sup> *Controlling the Bureaucracy*, LUMEN LEARNING, <https://courses.lumenlearning.com/amgovernment/chapter/controlling-the-bureaucracy/> (last visited June 5, 2019).

## **I. Detection and Diagnosis**

Each specific bio-agent demands a unique response. Properly responding to an anthrax attack, for instance, is very different than responding to a smallpox or plague attack.<sup>7</sup> Moreover, decisions must be made quickly to stanch a pandemic's spread. Being able to accurately and quickly detect and diagnose a bio-attack depends on having sophisticated capacities in place to gather, transmit, and analyze health and environmental data.

### ***Detection***

The earlier that a bio-attack is detected, the better. Yet, unlike an explosion or other conventional attack, a bio-attack will not be immediately obvious until disease symptoms are overwhelming. Even then, there will likely be confusion about which disease is causing those symptoms. The challenge, therefore, is obtaining accurate data quickly enough to mobilize an effective response.

#### **1. BioWatch for Sensing Pathogens**

Experts believe that bio-attack agents will likely be released in the air within highly trafficked indoor sites such as arenas, airports, and subway stations.<sup>8</sup> Programs managed by the Departments of Homeland Security and Health and Human Services are responsible for detection of a bio-attack.<sup>9</sup> To detect unusual releases, the DHS Office of Health Affairs BioWatch program places biosensors in major American cities that are connected to a national 24/7 early warning system.<sup>10</sup> Although DHS has not confirmed the exact number of cities engaged in the BioWatch program or the exact location of sensors, at least 31 cities are included in the BioWatch program, including Philadelphia, New York City, Washington, San Diego, Boston, Chicago, Miami, Atlanta, Detroit, Denver, San Francisco, Seattle, St. Louis, Houston and Los Angeles, with a goal of expanding to as many as 120 cities.<sup>11</sup>

The sensors test for anthrax, smallpox, plague, tularemia, and perhaps other agents, although the exact list is undisclosed.<sup>12</sup> Despite the biosensors, testing for bio-agents in the air is

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<sup>7</sup> Mark Keim & Arnold F. Kauffmann, *Principles for Emergency Response to Bioterrorism*, 34 ANNALS OF EMER. MED. 177, 181 (1999).

<sup>8</sup> Brian Naylor, *U.S. Bioterrorism-Detection Program is Unreliable, Report Finds*, NAT'L PUB. RADIO (Nov. 23, 2015), <https://www.npr.org/sections/thetwo-way/2015/11/23/457101931/u-s-bioterrorism-detection-program-is-unreliable-report-finds>.

<sup>9</sup> U.S. DEP'T OF HOMELAND SEC., *Detecting Bioterrorist Attacks*, <https://www.dhs.gov/biowatch-program> (last visited Jan. 17, 2019).

<sup>10</sup> *Id.*; See, e.g., U.S. DEP'T OF HOMELAND SEC. OFF. OF INSPECTOR GEN., *DHS' Management of BioWatch Program* (Jan. 2007), [http://www.oig.dhs.gov/assets/Mgmt/OIG\\_07-22\\_Jan07.pdf](http://www.oig.dhs.gov/assets/Mgmt/OIG_07-22_Jan07.pdf).

<sup>11</sup> DANA A. SHEA & SARAH A. LISTER, CONG. RESEARCH SERV., RL312152, THE BIOWATCH PROGRAM: DETECTION OF BIOTERRORISM (2003).

<sup>12</sup> *Id.*

extremely difficult.<sup>13</sup> A sensor that is too specific might neglect a dangerous release.<sup>14</sup> A sensor that is too broad, on the other hand, it might falsely react to something natural and benign.<sup>15</sup> DHS officials, therefore, are continuously trying to improve sensor capabilities.<sup>16</sup>

## 2. Programs for Reporting Unusual Diseases

Other than sensing pathogens, a bio-attack can be detected through reports of unusual disease outbreaks.<sup>17</sup> By accumulating reports of often-disparate symptoms, public health officials can identify a pattern that might suggest an epidemic.<sup>18</sup> *Biosurveillance* refers to a continuous process for monitoring the environment for markers of disease.<sup>19</sup> The key to biosurveillance is the systematic collection and analysis of data that can usefully characterize an event, as well as support an outbreak investigation.<sup>20</sup> The 2009 swine flu outbreak, for example, was initially signaled by a sudden increase in worker and student absenteeism in Veracruz, Mexico, along with elevated purchases of over-the-counter flu remedies.<sup>21</sup> In 2007, the 9/11 Commission Act required the development of the National Biosurveillance Integration Center (“NBIC”) to identify, characterize, localize and track biological events.<sup>22</sup> The Health Incident Surveillance Branch within the Health Threats Resilience Division of the DHS-OHA supervises the NBIC in coordination with 14 federal agencies.<sup>23</sup>

The BioSense program is another important component of biosurveillance. BioSense was initiated in 2003 as an integrated public health surveillance program managed by the Centers for Disease Control and Prevention (“CDC”).<sup>24</sup> Patient-anonymous data is collected from electronic

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<sup>13</sup> Kim E. Sapsford et al., *Sensors for Detecting Biological Agents*, 11 MATERIALSTODAY 38, 43 (2008).

<sup>14</sup> COMM. ON MAT’L & MFG. PROCESSES FOR ADVANCED SENSORS & RES. COUNCIL, NATIONAL SENSOR SYSTEMS FOR BIOLOGICAL AGENT ATTACKS: PROTECTING BUILDINGS AND MILITARY BASES, 6 (2005) (ebook).

<sup>15</sup> *Id.*

<sup>16</sup> *Supra* note 14 at 1.

<sup>17</sup> Stanley M. Lemon et al., *Global Infectious Disease Surveillance and Detection: Assessing the Challenges – Finding Solutions Workshop Summary*, INST. OF MED. OF NAT’L ACAD.S’ 2, [https://www.nap.edu/catalog/11996/global-infectious-disease-surveillance-and-detection-assessing-the-challenges-\(last visited May 29, 2019\)](https://www.nap.edu/catalog/11996/global-infectious-disease-surveillance-and-detection-assessing-the-challenges-(last%20visited%20May%2029%2C%202019).).

<sup>18</sup> Marc Lipsitch et al., *Improving the Evidence Base for Decision Making During a Pandemic: The Example of 2009 Influenza A/H1N1*, 9 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 89, 95 (2011).

<sup>19</sup> Nicholas Kman & Daniel Bachmann, *Biosurveillance: A Review and Update*, 2012 ADVANCES IN PREVENTATIVE MED., 2012, at 1.

<sup>20</sup> *Id.*

<sup>21</sup> Donald G. McNeil, Jr., *In New Theory, Swine Flu Started in Asia, not Mexico*, N.Y. TIMES, <https://www.nytimes.com/2009/06/24/health/24flu.html> (last visited Jan. 20, 2019).

<sup>22</sup> 6 U.S.C. § 195b(a) (2017).

<sup>23</sup> U.S. DEP’T OF HOMELAND SEC., *National Biosurveillance Integration Center*, [https://www.dhs.gov/sites/default/files/publications/2015-Factsheet-NBIC\\_0.pdf](https://www.dhs.gov/sites/default/files/publications/2015-Factsheet-NBIC_0.pdf) (last visited Jan. 17, 2019).

<sup>24</sup> *National Syndromic Surveillance Program*, CTRS. DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nssp/documents/NSSP-fact-sheet-508.pdf> (last visited Jan. 17, 2019).

health record systems, school absentee data, pharmacy data, food-borne outbreaks and other information sources for syndromic analysis.<sup>25</sup> State and local public health authorities have access to this secure data to aid in analysis; public health authorities may now designate BioSense for receiving syndromic surveillance test messages.<sup>26</sup>

The CDC, in turn, promotes disease reporting through the Public Health Information Network (“PHIN”), a network of information systems that optimizes electronic disease reporting with a common lexicon and technical requirements, and by promulgating an overall health information exchange architecture.<sup>27</sup> The National Electronic Disease Surveillance System is an Internet-based exchange architecture designed to enhance the PHIN by transferring appropriate public health, laboratory and clinical data efficiently and securely over the Internet to public health departments.<sup>28</sup> Notably, increased resources are being devoted to standards-based electronic messaging between stakeholders at multiple levels (providers, labs, local and state public health and CDC).<sup>29</sup>

The CDC's BioIntelligence Center (“BIC”) provides situational awareness of potential threats to local and state governments.<sup>30</sup> BIC analysts examine health data regarding 11 outbreak syndromes such as fever, rash, and gastrointestinal distress in order to detect unusual concentrations that might indicate a significant threat to public health.<sup>31</sup> When appropriate, the CDC director's Emergency Operations Center monitors the situation and coordinates data and analysis with the BIC.<sup>32</sup> The CDC also works to identify outbreaks with local and international

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<sup>25</sup> Deborah W. Gould et al., *The Evolution of BioSense: Lessons Learned and Future Directions*, PUB. HEALTH REP.S', <https://doi.org/10.1177/0033354917706954> (last visited June 6, 2019).

<sup>26</sup> Maximilian Wegener, *BioSense 2.0 Training Course Handbook*, NEV. OFF. OF PUB. HEALTH INFO. & EPIDEMIOLOGY 2, 4, 19 (Apr. 2015), <http://dpbh.nv.gov/uploadedFiles/dpbh.nv.gov/content/Programs/BioSense/dta/Training/Handbook%20for%20the%20BioSense2.0%20Training%20Course.pdf>.

<sup>27</sup> CTR.S' FOR DISEASE CONTROL & PREVENTION, *PHIN Tools and Resources*, <https://www.cdc.gov/phn/index.html> (last visited May 8, 2019).

<sup>28</sup> *National Electronic Disease Surveillance System: A Status Report on Implementation*, COUNCIL OF ST. & TERR. EPIDEMIOLOGISTS, <http://www.cste2.org/webpdfs/NEDSSassessmentCSTE2008.pdf> (last visited Jan. 17, 2019).

<sup>29</sup> *Id.*

<sup>30</sup> Colleen A. Bradley et al., *BioSense: Implementation of a National Early Event Detection and Situational Awareness System*, CTR.S' FOR DISEASE CONTROL & PREVENTION (Aug. 26, 2005), <https://www.ncbi.nlm.nih.gov/pubmed/16177687>.

<sup>31</sup> Daniel Neill & Karl Soetebier, *International Society for Disease Surveillance Conference 2011: Building a Future of Public Health Surveillance*, EMERGING HEALTH THREAT J. (Dec. 6, 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3261719/>.

<sup>32</sup> CTR.S' FOR DISEASE CONTROL & PREVENTION, *Public Health Preparedness: Strengthening CDC's Emergency Response* (Jan. 2009), [https://www.cdc.gov/cpr/publications/2009/phprep\\_report\\_2009.pdf](https://www.cdc.gov/cpr/publications/2009/phprep_report_2009.pdf).

partners.<sup>33</sup> The CDC Center for Global Health maintains regular relationships with the World Health Organization and numerous other national health departments and ministries.<sup>34</sup>

### **Diagnosis**

Whether natural or intentional, it is imperative to accurately diagnose a pandemic's cause in order to dispense effective countermeasures, to track its origin and spread, and to investigate potential perpetrators. Diagnosis of pathogens are coordinated by the CDC through the national Laboratory Response Network ("LRN").<sup>35</sup> The LRN is a nationwide network composed primarily of local, state, and federal government laboratories that provide confirmatory testing of potential bioterrorism pathogens in all 50 state public health labs and in additional locations.<sup>36</sup> Consensus protocols for testing were developed by the CDC, the FBI, and the Association of Public Health Laboratories prior to the anthrax mailings of 2001.<sup>37</sup>

In addition, the National Bioforensics Analysis Center ("NBFAC"), part of the National Biodefense Analysis and Countermeasures Center operated by the DHS in partnership with the FBI, is a central facility for analyzing biological samples in order to identify and attribute the use of biological weapons.<sup>38</sup> NBFAC has implemented a multi-faceted research and development program, established a stand-alone Safety and Biosecurity Program, Quality/Accreditation Program, and received select agent-handling certification from the CDC for all laboratory staff and facilities.<sup>39</sup> The NBFAC has also established a National Bioforensic Repository Collection with a comprehensive management plan and acquisition strategy to provide reference microbiological material against which suspect samples can be compared.<sup>40</sup>

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<sup>33</sup> CTR.S' FOR DISEASE CONTROL & PREVENTION, *CDC's Global Health Partnerships*, <https://www.cdc.gov/globalhealth/partnerships.htm> (last visited May 15, 2019).

<sup>34</sup> *Mission/Function Statement*, CTR. GLOB. HEALTH, <http://www.cdc.gov/maso/pdf/CGHfs.pdf> (last visited Jan. 17, 2019).

<sup>35</sup> CTR.S' FOR DISEASE CONTROL & PREVENTION, *Laboratory Response Network (LRN) Partners and Other Related Sites*, <https://emergency.cdc.gov/lrn/partners.asp> (last visited Jan. 17, 2019).

<sup>36</sup> See Mary J. R. Gilchrist, *A National Laboratory Network for Bioterrorism: Evolution from a Prototype Network of Laboratories Performing Routine Surveillance*, 165 MIL. MED. 28 (2000), and B.A. Perkins et al., *Public Health in the Time of Bioterrorism*, 8 EMERGING INFECTIOUS DISEASES 1015, 1015 (2002).

<sup>37</sup> HOLLY HARVEY, CONG. RESEARCH SERV., RL31719, AN OVERVIEW OF THE U.S. PUBLIC HEALTH SYSTEM IN THE CONTEXT OF BIOTERRORISM (2003).

<sup>38</sup> U.S. DEP'T OF HOMELAND SEC., *National Biodefense Analysis and Countermeasures Center*, [http://www.dhs.gov/files/labs/gc\\_1166211221830.shtm](http://www.dhs.gov/files/labs/gc_1166211221830.shtm) (last visited Jan. 17, 2019); See Vitko Jr., John, Director of Department of Homeland Security, National Biodefense Strategy, Congressional Testimony (July 28, 2005).

<sup>39</sup> Joseph I. Lieberman et al., *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*, BIPARTISAN REP. OF THE BLUE RIBBON STUDY PANEL ON BIODEFENSE 4, 9 (Oct. 2015), [https://www.researchgate.net/publication/283295565\\_A\\_National\\_Blueprint\\_For\\_Biodefense\\_Leadership\\_And\\_Major\\_Reform\\_Needed\\_To\\_Optimize\\_Efforts](https://www.researchgate.net/publication/283295565_A_National_Blueprint_For_Biodefense_Leadership_And_Major_Reform_Needed_To_Optimize_Efforts).

<sup>40</sup> See *Implementing the National Defense Strategy: Hearing Before the Subcomm. on Preventions of Nuclear Biological Attack of the H. Comm. on Homeland Sec., 109th Cong. (2005)*.

## II. Medical Countermeasures

Unlike most other disasters that require generic treatment of injuries due to blast and fire, treating victims of bio-attacks requires rapid and targeted application of specific medical countermeasures (“MCM”) such as vaccines and antidotes.<sup>41</sup> Doing this effectively poses two challenges:

1. Many MCMs need to be developed or improved, entailing substantial research and testing;
2. MCMs need to be securely stockpiled, distributed to attack sites, and disseminated to victims under conditions of extreme stress.

### *MCM Development*

Producing MCMs against bio-attacks brings several risks. Developing MCMs against many different pathogens is scientifically challenging; the market for useful products is extremely uncertain; and large research and development investments might never bring a fair return.<sup>42</sup> Project BioShield, the comprehensive system for MCM preparedness, is organized around three main aspects:

1. Funding and procurement;
2. Facilitation of R&D; and
3. Facilitation of countermeasure use in an emergency.<sup>43</sup>

A complex bureaucracy, administered by HHS through the office of the assistant secretary for preparedness and response (“ASPR”) is responsible for incentivizing MCM preparedness.<sup>44</sup> The National Institutes of Health (“NIH”) and the National Institute of Allergy and Infectious Diseases (“NIAID”) have primary responsibility to see that promising drug candidates are awarded contracts through Project BioShield’s funds.<sup>45</sup> The Institutes’ approach is known as the “push”

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<sup>41</sup> U.S. FOOD & DRUG ADMIN., *What are Medical Countermeasures?*, <https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/what-are-medical-countermeasures> (last visited May 15, 2019).

<sup>42</sup> THERESA WIZEMANN ET AL., INST. OF MED. OF THE NAT’L ACAD.S’ OF SCI.S’ ENG’G & MED., *RAPID MEDICAL COUNTERMEASURE RESPONSE TO INFECTIOUS DISEASES: ENABLING SUSTAINABLE CAPABILITIES THROUGH ONGOING PUBLIC - AND PRIVATE-SECTOR PARTNERSHIPS: WORKSHOP SUMMARY*, (2016).

<sup>43</sup> U.S. FOOD & DRUG ADMIN., *MCM-Related Counterterrorism Legislation*, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation> (last visited June 6, 2019).

<sup>44</sup> *HHS Office of the Assistant Secretary for Preparedness and Response* (Dec. 20, 2018), <https://www.phe.gov/about/aspr/pages/default.aspx>.

<sup>45</sup> Barry Kellman & Zachary D. Clopton, *A Global Architecture for Medical Counter-Measure Preparedness Against Bioviolence*, 6 U. ST. THOMAS L.J. 550, 557 (2009); See also *The NIH Almanac*, NAT’L INST. OF

incentive because it tries to set in motion the wheels of research and expedite reviews of promising biodefense drugs through the application process.<sup>46</sup>

Within ASPR, the Biomedical Advanced Research and Development Authority (“BARDA”) oversees and coordinates the research and acquisition of MCMs and is primarily responsible for facilitating communication between the federal government and the biomedical industry.<sup>47</sup> For MCMs at an advanced level of development, the BioShield Special Reserve Fund enables BARDA to purchase and stockpile MCMs while simultaneously providing funding for their research and development, as well as providing the manufacturer with a guaranteed purchaser — the United States government.<sup>48</sup> The Medical Countermeasure Development Fund, separate and in addition to the BioShield Special Reserve Fund, allows BARDA authorities to sponsor innovative research to improve MCMs.<sup>49</sup>

When a promising MCM is developed, the Public Health Emergency Medical Countermeasures Enterprise (“PHEMCE”), overseen by BARDA as a multi-agency collaborative “enterprise”, determines its requirements and prioritizes development and acquisition programs.<sup>50</sup> Through the use of milestone contracts that allow companies to receive payments prior to final delivery of the goods, BARDA/PHEMCE can review the progress and determine whether the work is satisfactory so that promising drugs may be appropriately transitioned for additional funding.<sup>51</sup>

The Department of Defense has complementary programs: the Defense Threat Reduction Agency’s Transformational Medical Technologies Initiative program seeks to develop broad-spectrum defenses against bacterial pathogens and hemorrhagic fevers; the Defense Advanced Research Projects Agency’s Accelerated Manufacture of Pharmaceuticals program is authorized

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ALLERGY & INFECTIOUS DISEASE, <https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-institute-allergy-infectious-diseases-niaid> (last updated Mar. 1, 2017).

<sup>46</sup> THERESA WIZEMANN ET AL., INST. OF MED. OF THE NAT’L ACAD.S’, THE PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE: INNOVATIVE STRATEGIES TO ENHANCE PRODUCTS FROM DISCOVERY THROUGH APPROVAL: WORKSHOP SUMMARY 39-40, 124, 142 (2010).

<sup>47</sup> U.S. DEP’T OF HEALTH & HUM. SERV., *BARDA Strategic Plan 2011-2016*, BIOMEDICAL ADVANCED RES. & DEV. AUTH. 4 (Oct. 4, 2011), <https://www.phe.gov/about/barda/Documents/barda-strategic-plan.pdf>.

<sup>48</sup> U.S. DEP’T OF HEALTH & HUM. SERV., *Project Bioshield Overview*, <https://www.medicalcountermeasures.gov/barda/cbrn/project-bioshield-overview.aspx> (last visited May 15, 2019).

<sup>49</sup> *Id.*

<sup>50</sup> Barry Kellman & Zachary D. Clopton, *A Global Architecture for Medical Counter-Measure Preparedness Against Bioviolence*, 6 U. ST. THOMAS L.J. 550, 556 (2009); See U.S. DEP’T OF HEALTH & HUM. SERV., *Implementation Plan for Chemical, Biological, Radiological, and Nuclear Threats*, HHS PUB. HEALTH EMER. MED. COUNTERMEASURE ENTER. 5-6 (Apr. 2007), <https://www.phe.gov/Preparedness/mcm/phemce/Documents/2007-phemce-implementation.pdf>.

<sup>51</sup> U.S. DEP’T OF HEALTH & HUM. SERV., *Project Bioshield Funding*, <https://www.medicalcountermeasures.gov/barda/cbrn/project-bioshield-overview/project-bioshield-funding.aspx> (last visited May 15, 2019).



to create a system for producing 3 million doses of vaccines or monoclonal antibodies within twelve (12) weeks.<sup>52</sup>

While Project BioShield was initially funded with \$5.6 billion, some of that funding has since been transferred to basic research and development of antiviral medications against the flu.<sup>53</sup> One reason for these transfers is that BioShield has had very limited success, generating only a handful of useful MCMs.<sup>54</sup> Most experts give BioShield credit for alleviating some bureaucratic and financial impediments to developing MCMs and attribute its lack of success to the scientific complexity of discovering safe and effective medicines against threatening scourges.<sup>55</sup>

### ***New Vaccine Production Capacities***

The government's efforts to increase medical countermeasures' production have had some success. A recently opened vaccine production facility in North Carolina is owned and managed by Novartis; the Department of Health and Human Services contributed 49 percent toward the facility's total investment of nearly \$1 billion.<sup>56</sup> The facility produces vaccines using cultured canine kidney cells (instead of the traditional chicken eggs) to grow a vaccine—as much as 50 million doses.<sup>57</sup> Use of tissue culture instead of eggs reduces the danger of contamination and increases capacities for rapid mass production of vaccine.<sup>58</sup> The new facility might reduce production times from five months to four, although there is dispute among experts if the new facility will in fact reduce production times by that much.<sup>59</sup> There is also some disagreement about the impact of reduction times, with proponents emphasizing the ability to incorporate new

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<sup>52</sup> *Defense Threat Reduction Agency: Chemical/Biological Technologies*, DEF. THREAT REDUCTION AGENCY, <http://www.dtra.mil/Research/Chemical-Biological-Technologies/> (last visited Feb. 12, 2019); Gigi Kwik Gronvall et al., *Flexible Defenses Roundtable Meeting: Promoting the Strategic Innovation of Medical Countermeasures*, 5 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC., & SCI. 271, 274 (2007).

<sup>53</sup> U.S. DEP'T OF HEALTH & HUM. SERV., *Project Bioshield Overview*, <https://www.medicalcountermeasures.gov/barda/cbrn/project-bioshield-overview/> (last updated Oct. 18, 2018); See also FRANK GROTON, CONG. RESEARCH SERV., R41033, PROJECT BIOSHIELD: APPROPRIATIONS, ACQUISITIONS, AND ISSUES FOR CONGRESS (2011).

<sup>54</sup> NUCLEAR THREAT INITIATIVE, *Q&A: Bioshield Program Successful After "Rocky Start," HHS Preparedness Chief Says*, <https://www.nti.org/gsn/article/q-bioshield-program-successful-after-rocky-start-hhs-preparedness-chief-says/> (last visited May 15, 2019).

<sup>55</sup> See Wil S. Hylton, *How Ready are we for Bioterrorism?*, N.Y. TIMES (Oct. 26, 2011), <https://www.nytimes.com/2011/10/30/magazine/how-ready-are-we-for-bioterrorism.html>.

<sup>56</sup> Robert Roos, *Novartis Unveils US Cell-Based Flu Vaccine Plant*, U. OF MINN. CTR. FOR INFECTIOUS DISEASE RES. & POL'Y (Nov. 24, 2009), <http://www.cidrap.umn.edu/news/perspective/2009/11/novartis-unveils-us-cell-based-flu-vaccine-plant>. See also *\$486M Novartis Plant Funded*, N.C. BIOTECHNOLOGY CTR. (Jan. 15, 2009), <https://www.ncbiotech.org/news/486m-novartis-plant-funded>.

<sup>57</sup> *Id.* See also Karie Youngdahl, *U.S. Cell Line Facility to Produce Pandemic Influenza Vaccine*, THE HIST. OF VACCINES (Dec. 13, 2011), <https://www.historyofvaccines.org/content/blog/us-cell-line-facility-produce-pandemic-influenza-vaccine>.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

data about the disease in-to the vaccine.<sup>60</sup> Other experts point out that, even at four months, a sudden and acute pandemic would already be in its second stage.<sup>61</sup>

In addition, Medicago, recently opened a new vaccine production facility with a \$21 million contract from the Defense Advanced Research Projects Agency, which makes a vaccine from virus-like particles of certain tobacco leaves.<sup>62</sup> In this process, only 30 days are required to develop vaccines.<sup>63</sup> This process may also have the advantage of reducing the cost and timing of vaccine production.<sup>64</sup> In any event, the next stage in vaccine production involves the use of recombinant technology that is forecast to reduce production times to 12 weeks, though this capability is at least two years away.<sup>65</sup>

### ***Stockpile Planning, Distribution and Dispensation***

Surge capacity to produce MSMs does not currently exist when a bio-attack occurs. Therefore, MCMs must be produced in advance and stored in the Strategic National Stockpile (“SNS”) – a network of warehouses holding stores of medicines and equipment for distribution during emergencies.<sup>66</sup> Locations and contents of specific countermeasures are kept secret for security reasons, but certainly include countermeasures for common bioterrorism threats such as vaccines for anthrax, smallpox and tularemia.<sup>67</sup> Because MCMs must be maintained under strict temperature and other constraints, elaborate plans for the SNS have been developed by BARDA; the CDC manages the stockpile with support of BARDA, DHS and United States Department of Defense (“DoD”).<sup>68</sup>

When a disease emergency is declared, the affected state’s governor must request delivery of MCMs, although in cases of national emergency the president can assume this responsibility.<sup>69</sup> CDC officials, in coordination with officials of the Federal Emergency Management Agency (FEMA) as well as state and local officials, are authorized to evaluate the situation, determine the

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<sup>60</sup> *Id.*

<sup>61</sup> See Mitchel L. Zoler, *Flu Vaccine Facility May not Speed Production*, SKIN & ALLERGY NEWS, Feb. 1, 2012, at 34.

<sup>62</sup> Frank Vinluan, *Medicago’s RTP Vaccine Facility Opens to Address Pandemics*, MEDCITY NEWS (Nov. 14, 2011), <http://www.medcitynews.com/2011/11/medicagos-rtp-vaccine-facility-opens-to-address-pandemics/>.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> *Plant-Derived Vaccines*, BIOPHARMA DEALMAKERS (Jul. 20, 2018), <https://biopharmadealmakers.nature.com/users/114926-medicago/posts/37798-plant-derived-vaccines>.

<sup>66</sup> Barry Kellman & Zachary D. Clopton, *A Global Architecture for Medical Counter-Measure Preparedness Against Bioviolence*, 6 U. ST. THOMAS L.J. 550, 557 (2009).

<sup>67</sup> *Anthrax, Smallpox, and Bioterrorism*, THE VACCINE PAGE, <http://vaccines.org/bioterrorism.html> (last visited Feb. 11, 2019).

<sup>68</sup> James T. Need, *Strategic National Stockpile Program: Implications for Military Medicine*, 171 MIL. MED. 698, 698 (2006).

<sup>69</sup> *Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: Version 11*, CTR.S’ FOR DISEASE CONTROL 30, 72-73, [https://www.orau.gov/sns/v11/ReceivingDistributingDispensingSNSAssets\\_V11.pdf](https://www.orau.gov/sns/v11/ReceivingDistributingDispensingSNSAssets_V11.pdf) (last visited Feb. 5, 2019).

most prudent action, and prioritize MCM dispensation.<sup>70</sup> Under current plans, supplies from the SNS will be distributed to affected areas rapidly through push packages – government-owned caches of supplies and medications – within twelve (12) hours via either trucks or commercial cargo aircraft.<sup>71</sup> Concurrently, the SNS Program will deploy its Stockpile Service Advance Group to coordinate with state and local officials so that the SNS assets can be efficiently received and distributed upon arrival at the site.<sup>72</sup>

There is ongoing debate about what is the best method of dispensing MCMs to the public.<sup>73</sup> Until relatively recently, plans have called for dispensation from central locations such as schools and community centers.<sup>74</sup> This has the advantage of putting the MCMs into the hands of state and local health departments who have been trained on the reception, protection and dispensation of these supplies. There are, however, disadvantages, especially for people with challenged mobility or living far from urban centers. Moreover, central dispensation assumes that emergency responders are able to work and that there is a command and control system to effectively guide the process. In a dire emergency, these assumptions might not be realistic.<sup>75</sup>

For some MCMs – especially those that can be self-administered – an alternative to centralized dispensation is to get them to each household, typically through postal delivery. This is far more convenient for house-bound citizens. Moreover, inducing people to stay in their homes is important to reduce the spread of contagious disease; it obviously makes sense to avoid having them come to a central site to get their medicine. However, not all medication can be self-administered, and effective household delivery does not ensure that the medication will be taken correctly. While an advance delivery of medicine and substantial information on proper use can alleviate some of these problems, certain medication has a short shelf life – delivering them in advance of an emergency might not be effective. Altogether, officials are weighing many different options, none of which are perfect.

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<sup>70</sup> *Biological Incident Annex to the Response and Recovery Federal Interagency Operations Plans Final - January 2017*, FED. EMER. MGMT. AGENCY, [https://www.fema.gov/media-library-data/1511178017324-92a7a7f808b3f03e5fa2f8495bdfe335/BIA\\_Annex\\_Final\\_1-23-17\\_\(508\\_Compliant\\_6-28-17\).pdf](https://www.fema.gov/media-library-data/1511178017324-92a7a7f808b3f03e5fa2f8495bdfe335/BIA_Annex_Final_1-23-17_(508_Compliant_6-28-17).pdf) (last visited Feb. 5, 2018).

<sup>71</sup> U.S. DEP'T OF HEALTH & HUM. SERV., *Stockpile Responses*, <https://www.phe.gov/about/sns/Pages/responses.aspx> (last visited May 15, 2019).

<sup>72</sup> *2016 SNS Preparedness Course - SNS Overview*, CTR.S' FOR DISEASE CONTROL & PREVENTION, [https://ftp.cdc.gov/pub/MCMTraining/SNS%20Prep%20Workbook%20for%20iPads\\_2016/Tab%201%20-%20SNS\\_Overview\\_508%20\(June%202015\).pdf](https://ftp.cdc.gov/pub/MCMTraining/SNS%20Prep%20Workbook%20for%20iPads_2016/Tab%201%20-%20SNS_Overview_508%20(June%202015).pdf) (last visited Jan. 17, 2019).

<sup>73</sup> *See How to Steward Medical Countermeasures and Public Trust in an Emergency: A Communication Casebook for FDA and its Public Health Partners*, UPMC CTR. FOR HEALTH SEC. (Nov. 2016), [http://www.centerforhealthsecurity.org/our-work/events/2016%20FDA%20MCM/FDA\\_Casebook.pdf](http://www.centerforhealthsecurity.org/our-work/events/2016%20FDA%20MCM/FDA_Casebook.pdf).

<sup>74</sup> U.S. DEP'T OF HOMELAND SEC., *Strategic National Stockpile Distribution Planning: Selecting Facilities for Use as Dispensing Sites*, <https://www.hsd1.org/?view&did=765467> (last visited May 15, 2019).

<sup>75</sup> *See* INST. OF MED. OF THE NAT'L ACAD.S', *Dispensing Medical Countermeasures for Public Health Emergencies: Workshop Summary*, [https://www.ncbi.nlm.nih.gov/books/NBK4111/pdf/Bookshelf\\_NBK4111.pdf](https://www.ncbi.nlm.nih.gov/books/NBK4111/pdf/Bookshelf_NBK4111.pdf) (last visited June 6, 2019).

### **III. Response and Restoration of Order**

In many respects, responses to bio-attacks will be similar to any catastrophe. For example, as part of the normal National Response Framework, a governor can request the president to declare a state of emergency, which triggers FEMA's authority under the Federal Emergency Response Plan, pursuant to the National Incident Management System, to provide technical and advisory assistance, funds and supplies.<sup>76</sup> Yet, bio-attacks pose a unique threat that cannot be adequately addressed with normal emergency declaration processes because of the intensive need for specialized responses. In connection with bio-attacks, three aspects of consequence mitigation and order restoration deserve special attention.

#### ***Use of Military Forces***

Generally, emergency responses do not involve the direct use of military forces because of restrictions imposed in the Posse Comitatus Act and the Stafford Act.<sup>77</sup> National Guard units, however, may be used under the direction of their state's governor because state militias are not generally bound by the Posse Comitatus Act.<sup>78</sup> In response to bio-attacks, however, the U.S. attorney general may request assistance from the defense secretary because of the immediate need for specialized materials and training.<sup>79</sup> The U.S. attorney general and the defense secretary must jointly determine that the biological weapon poses "a serious threat to the interest of the United States" according to the following three factors:

1. Civilian expertise and capabilities cannot immediately counter the threat;
2. The Defense Department's capabilities are necessary to counter the threat; and,
3. Enforcement of the laws against weapons of mass destruction would be impaired if the Defense Department was not allowed to act.<sup>80</sup>

The President also has the authority to use the military in order to alleviate the demands on local law enforcement in cases of a biological attack.<sup>81</sup>

#### ***Public Health Mobilization***

While the CDC has as an essential role in sharing information and providing both resources and expertise, the primary responsibility of a public health response will rest upon the public health departments of individual states. These departments, through the governor's authority, can

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<sup>76</sup> *National Response Framework: List of Authorities and References*, FED. EMER. MGMT. AGENCY, <https://www.fema.gov/pdf/emergency/nrf/nrf-authorities.pdf> (last visited Feb. 5, 2019).

<sup>77</sup> 18 U.S.C. § 1385 (2017); 42 U.S.C. §§ 5121-5207 (2017).

<sup>78</sup> JENNIFER K. ELSEA, CONG. RESEARCH SERV., R42669, THE POSSE COMITATUS ACT AND RELATED MATTERS: THE USE OF THE MILITARY TO EXECUTE CIVILIAN LAW 61-62 (2018).

<sup>79</sup> *National Response Framework*, U.S. DEP'T OF HOMELAND SEC., [https://www.fema.gov/media-library-data/1466014682982-9bcf8245ba4c60c120aa915abe74e15d/National\\_Response\\_Framework3rd.pdf](https://www.fema.gov/media-library-data/1466014682982-9bcf8245ba4c60c120aa915abe74e15d/National_Response_Framework3rd.pdf) (last visited Jan. 15, 2019).

<sup>80</sup> 10 U.S.C. § 382 (2017); 18 U.S.C. § 175 (2017); 18 U.S.C. § 2332(e) (2017).

<sup>81</sup> 50 U.S.C. § 2316(d) (2017).

implement restrictions after an emergency is declared and conduct a large portion of laboratory testing. Moreover, states' public health departments will likely coordinate mass casualty treatment and care.

Local public health departments have a critical role in public messaging, the operation of local clinics and information sharing among medical institutions. Public messaging will likely include information on best practices for limiting the spread of disease and other advisories. They may be the first to identify local public health impacts and have a responsibility to notify state and federal agencies.<sup>82</sup>

In the case of a biological attack, the traditional command and control under the National Incident Management System mentioned earlier will remain in place.<sup>83</sup> Public health authorization is required for movement restrictions at the state level and for stockpile distribution at the federal level, and offers other protections.<sup>84</sup> Because other agencies may not have the same specialized knowledge about protection from pathogens, treatment protocols or a technical understanding of disease spread, public health departments are likely to take the lead in response priorities and will likely encounter great deference.

### ***Restricting Movement***

If a contagious agent is used in a bio-attack, the need to stanch the spread of disease may require a quarantine, restrictions on travel, curfews, the closing of borders, and cancellation of public gatherings.<sup>85</sup> Most states authorize the governor to declare martial law during an emergency and take personal property, subject to constitutional guarantees of fair compensation.<sup>86</sup> Governors also have broad authority to reallocate the use of publicly owned facilities.<sup>87</sup> It may be necessary for example, to convert public schools into sheltering, triage or command and control centers. Typically, there is a defined statutory period during which the governor may act in consultation with the state's public health department but without legislative approval.<sup>88</sup>

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<sup>82</sup> JO I. BOUFORD ET AL., THE FUTURE OF PUBLIC HEALTH IN THE 21ST CENTURY, INST. OF MED. OF NAT'L ACAD.S', 141 (2002).

<sup>83</sup> Gregory Sunshine, *Symposium: The Case for Streamlining Emergency Declaration Authorities and Adapting Legal Requirements to Ever-Changing Public Health Threats*, 67 EMORY L.J. 397, 397 (2018).

<sup>84</sup> INST. OF MED. OF NAT'L ACAD.S', *The Future of the Public Health in the 21st Century*, THE GOVERNMENTAL PUB. HEALTH INFRASTRUCTURE, <https://www.ncbi.nlm.nih.gov/books/NBK221231/> (last visited Jan. 15, 2019).

<sup>85</sup> *Biological Index Annex*, FED. EMER. MGMT. AGENCY, [https://www.fema.gov/pdf/emergency/nrf/nrf\\_BiologicalIncidentAnnex.pdf](https://www.fema.gov/pdf/emergency/nrf/nrf_BiologicalIncidentAnnex.pdf) (last visited Jan. 15, 2019).

<sup>86</sup> *Constitutional Topic: Martial Law*, THE U.S. CONST. ONLINE, [https://www.usconstitution.net/consttop\\_mlaw.html](https://www.usconstitution.net/consttop_mlaw.html) (last visited Jan. 15, 2019).

<sup>87</sup> *A Governor's Guide to Homeland Security*, NGA CTR. FOR BEST PRAC.S', <http://www.npstc.org/documents/070314GovGuideHS.pdf> (last visited Jan 15, 2019).

<sup>88</sup> INST. OF MED., *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response*, <https://www.ncbi.nlm.nih.gov/books/NBK201063> (last visited May 15, 2019).

Although federal authority requires more statutory certainty, various executive authorities have similarly broad powers in the correct conditions. The Surgeon General may, with the approval of the Secretary of the Department of Health and Human Services, make rules to prevent interstate and international transmission of disease including issuing orders to apprehend and detain those believed to be infected by disease.<sup>89</sup> This authority does not extend to local quarantines, but the HHS secretary may cooperate and aid local officials in setting up their quarantines.<sup>90</sup>

Whenever a restriction such as a quarantine or evacuation is ordered, there will be some noncompliance. Judgments must be made to determine the amount of force allowed to enforce the restrictions: the force appropriate for a precautionary quarantine, as supposed to preventing the spread of a disease that could result in the deaths of hundreds of millions, will be dramatically different. With the societal stress, traditional crimes like looting and robbery will become more likely. Responders who must use force are only held liable if their actions constituted unreasonably excessive force given what the responder was aware of at the time.

#### **IV. Conclusion**

Planning bio-attack responses must address the risks that an attacker can cause huge catastrophe using a variety of attack agents and release methods. Yet, bio-attacks have happened only once – the 2001 anthrax attacks.<sup>91</sup> There is scant evidence on which to predict how a response to such potentially distinctive high-consequence events will unfold on a large scale. Moreover, the maze of bureaucratic responsibility for responding to bio-attacks means that no centralized authority (short of the president) will exercise over-arching command and control. Indeed, federal responsibilities are spread among various offices in the DHS and HHS, with support from the attorney general, surgeon general, and Defense Department.<sup>92</sup> However, the response is not entirely federal and local officials also have critical roles in responses. On top of all this is the likely unprecedented panic that a bio-attack will provoke. All these factors – lack of experience, mass consequences and panic, variable conditions and attack modes, and overlapping responsibilities -- will make it difficult to sort out the facts of a bio-attack. The key to success is preparation.

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<sup>89</sup> 42 U.S.C. § 264 *et seq.* (2017).

<sup>90</sup> 42 U.S.C. § 243 (2017).

<sup>91</sup> *Supra* note 69.

<sup>92</sup> ASS'N OF ST. & TERR. HEALTH OFFICIALS, *Strategic National Stockpile*, <http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Use-Authorization-Toolkit/Strategic-National-Stockpile-Fact-Sheet/> (last visited May 15, 2019).